



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3435-FN]

Medicare and Medicaid Programs: Application from the Center for Improvement in Healthcare Quality for Initial CMS-Approval of its Critical Access Hospital Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces our decision to approve the Center for Improvement in Healthcare Quality for initial recognition as a national accrediting organization for critical access hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: The decision announced in this notice is applicable June 1, 2023 to June 1, 2027.

FOR FURTHER INFORMATION CONTACT:

Caecilia Blondiaux, (410) 786-2190.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a critical access hospital (CAH) provided certain requirements are met. Sections 1820(c)(2)(B), 1820(e) and 1861(mm)(1) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a CAH. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 485, subpart F, specify the conditions of participation (CoPs) that a CAH must meet to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for CAHs. The regulations at 42 CFR 485.647 specify that a CAH's psychiatric or rehabilitation distinct part

unit (DPU), if any, must meet the hospital requirements specified in subparts A, B, C, and D of part 482 and selected provisions of 42 CFR part 412 in order for the CAH DPU to participate in the Medicare program.

Prior to becoming a CAH, to enter into an agreement, a CAH must first be certified by a state survey agency as a hospital complying with the conditions or requirements at part 482, then can convert to a CAH by complying with the conditions or requirements at part 485, subpart F. The CAH is subject to regular surveys by a state survey agency to determine whether it continues to meet these requirements. However, there is an alternative to surveys by state agencies. Certification by a nationally recognized accreditation program can substitute for ongoing state review.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national accrediting organization (AO) that all applicable Medicare requirements are met or exceeded, we will deem those provider entities as having met such requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services (the Secretary) as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare requirements. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare requirements.

Our regulations concerning the approval of AOs are at §§ 488.4 and 488.5. The regulations at § 488.5(e)(2)(i) require an AO to reapply for continued approval of its accreditation program every 6 years or sooner, as determined by CMS. This notice is to announce our initial approval of the Center for Improvement in Healthcare Quality's (CIHQ's)

CAH accreditation program. CIHQ's CAH deeming authority will be reviewed for continued approval in accordance with the regulations at §§ 488.4 and 488.5 after this initial term of approval.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

On December 7, 2022, we published a proposed notice in the **Federal Register** (87 FR 75049), announcing CIHQ's request for initial approval of its Medicare critical hospital accreditation program. In the December 2022 proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5, we conducted a review of CIHQ's Medicare CAH accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- A virtual administrative review of CIHQ's: (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and, (5) survey review and decision-making process for accreditation.
- A comparison of CIHQ's accreditation to our current Medicare CAH CoPs.

- A documentation review of CIHQ's survey process to:

- ++ Determine the composition of the survey team, surveyor qualifications, and CIHQ's ability to provide continuing surveyor training.

- ++ Compare CIHQ's processes to those of state survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

- ++ Evaluate CIHQ's procedures for monitoring CAH out of compliance with CIHQ's program requirements. The monitoring procedures are used only when CIHQ identifies noncompliance. If noncompliance is identified through validation reviews, the state survey agency monitors corrections as specified at § 488.7(d).

- ++ Assess CIHQ's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

- ++ Establish CIHQ's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

- ++ Determine the adequacy of staff and other resources.

- ++ Confirm CIHQ's ability to provide adequate funding for performing required surveys.

- ++ Confirm CIHQ's policies with respect to whether surveys are announced or unannounced.

- ++ Obtain CIHQ's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

IV. Analysis of and Responses to Public Comments on the Proposed Notice

In accordance with section 1865(a)(3)(A) of the Act, the December 7, 2022 proposed notice also solicited public comments regarding whether CIHQ's requirements met or exceeded the Medicare CoPs for CAHs. We received one comment, which was out of the scope of the proposed notice.

V. Provisions of the Final Notice

A. Differences Between CIHQ's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared CIHQ's CAH requirements and survey process with the Medicare CoPs and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of CIHQ's CAH application were conducted as described in section III of this notice and has yielded the following areas where, as of the date of this notice, CIHQ's has completed revising its standards and certification processes in order to--

- Meet the standard's requirements of all of the following regulations:

- ++ Section 485.604(a)(2), to clarify the requirements for clinical nurse specialists' education, including a master's or doctoral level degree in a defined clinical area of nursing from an accredited educational institution.

- ++ Section 485.616(c)(4)(iv), to specify the requirement of an internal review of a distant-site physician's or practitioner's performance under privileges at the CAH whose patients are receiving the telemedicine services from the physician or practitioner.

- ++ Section 485.623(b)(1), to ensure that all essential mechanical, electrical and patient care equipment is maintained in safe operating condition.

- ++ Section 485.623(c)(1)(i), to align CIHQ's comparable standards with the Life Safety Code (LSC) (National Fire Protection Association (NFPA) 101 and Tentative Interim Amendments (TIAs): TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4).

- ++ Section 485.627(a), to include additional clarification or specific language on "determining, implementing and monitoring policies governing the CAH's total operation".

- ++ Section 485.635(b)(3), to include reference to state law within its standard for radiology services.

- ++ Section 485.638(a)(4)(iv), to specify the qualifications of who may make entries into the medical record, which must be dated, and signed by the individual who made the entry.

++ Section 485.639(a), to further expand on the qualifications on the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with state scope of practice laws.

In addition to the standards review, CMS also reviewed CIHQ's comparable survey processes, which were conducted as described in section III of this notice, and yielded the following areas where, as of the date of this notice, CIHQ has completed revising its survey processes in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

- Revising CIHQ's surveyor guide to ensure a comprehensive review of environmental safety and life safety requirements are performed.
- Clarifying CIHQ's policies to align with the SOM Appendix A-Hospitals, Survey Protocol, Task 3, Survey Locations, and Appendix W-CAHs Entrance Activities, to include that all hospital departments and services at the primary hospital campus and remote locations, satellite locations, inpatient care locations, out-patient surgery locations, complex out-patient care locations, and a select sample of each type of other services provided at additional provider based locations, including contracted patient care activities or patient services will be surveyed. These facility types may have occupancy classifications other than healthcare or ambulatory occupancies, as determined by the LSC.
- Updating CIHQ's position summaries and description to include that the LSC surveyor's responsibilities is comprised of an assessment of both the LSC and Health Care Facilities Code.

B. Term of Approval

Based on our review and observations described in sections III and V of this notice, we approve CIHQ as a national AO for CAHs that request participation in the Medicare program. The decision announced in this notice is effective June 1, 2023 through June 1, 2027 (4 years).

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et.seq.).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: May 17, 2023.

Evell J Barco Holland,

Federal Register Liaison,

Centers for Medicare & Medicaid Services.

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